

Appl. No. : 10/608,903  
Filed : June 27, 2003

### REMARKS

Claim 3 has been cancelled. Claims 1-2 have been amended. New claims 4-5 are added. Claims 1-2 and 4-5 are now pending in this application. Support for the amendments is found in the existing claims and the specification as discussed below. Accordingly, the amendments do not constitute the addition of new matter. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

#### Election/Restriction

Applicant hereby confirms election of Group I, claims 1-2. Claim 3 is cancelled with this amendment without prejudice or disclaimer. Applicant reserves the right to file a divisional application.

#### Specification

The specification has been amended to capitalize  $\zeta$ -GRIP<sup>TM</sup> at each occurrence and to provide a generic description at the first occurrence at paragraph 0019.

The abbreviation of PDVF has been corrected to PVDF at paragraph 0019 and the term has been spelled out at its first occurrence. Likewise, the full names for the abbreviations SSA/RO, SLE, and BNCIP has been provided in paragraph 0026.

In view of Applicant's amendments, withdrawal of the objection to the specification is respectfully requested.

#### Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-2 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of detection of SSA/RO antigens from SLE patients serum, does not reasonably provide enablement for all disease or autoimmune antigens in all mammals. The Examiner argues that the art is unpredictable with regards to prediction of disease/autoimmune state and that undue experimentation would be required to make and use the invention commensurate in scope with the claims.

Applicant respectfully disagrees. The claimed invention is directed to an antigen/antibody assay that is analogous to an enzyme linked immunoassay. In order to clarify the invention, claim 1 has been amended to recite that the method is directed to detecting the presence of an antibody. Support is found throughout the present specification. See for example,

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paragraph 0021 of the present specification. One skilled in the art knows how to react an antigen with an antibody and then react the complex with a second antibody. Clearly, the practice of the invention is not dependent upon the specific antigen/antibody pair selected and can be practiced with any antibody/ antigen combination, including those used in disease detection. One skilled in the art would reasonably expect the claimed detection system to work with virtually any antigen/antibody combination.

The limitation that the antibody detection is indicative of a disease state is now found in new claim 4 and Applicants maintain that this claim is enabled broadly for immunoassays used in disease detection as claimed. Support for claim 4 is found in paragraph 0030 and in original claim 1. While disease and autoimmune detection may be complex and involve multiple antibodies as stated in the Office Action, nonetheless many useful assays have been developed which rely upon detection of a single antigen or antibody as an indicator of a disease state. For example, where diagnosis is difficult and complex, more than one assay may be required for a definitive diagnosis. While the skilled practitioner may not rely upon a single assay, nevertheless each test performed is evaluated and is useful in formulating a final diagnosis. One skilled in the art would know that the immunoassay detection method as claimed could be used for any diagnostic immunoassay to detect a positive or negative reaction. Accordingly, Applicant respectfully submits that one skilled in the art could practice the invention as claimed with any antigen/antibody combination, including immunoassays which are indicative of a disease state, without undue experimentation.

Claim 5 has been added which is directed specifically to SLE which the Examiner has indicated as enabled. Accordingly, claim 5 at least is free of this ground of rejection. Support for claim 5 is found particularly in paragraph 0042 of the present specification.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

**Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-2 are rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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On page 6 at section 8 of the Office Action , the Examiner rejects the claims as indefinite. The Examiner's points are addressed in the Amendment.

The preamble of claim 1 has been amended to recite that the method is for detecting the presence of an antibody. Claim 1, line 3 has been amended to clarify that an antigen is immobilized.

At claim 1, lines 11 and 12, the claim has been amended to more specifically recite that the current indicates "binding of the metal-antibody conjugate to the antibody bound to the immobilized antigen". Support for the amendments to claim 1 are found particularly in paragraph 0021 of the present specification.

Regarding the phrase "under conditions such" in claim 2, the claim has been amended to recite "under conditions such that any antigen present in the sample binds to said immobilized antibody to form an immobilized antibody-bound antigen complex". Applicant would also like to clarify that the phrase "under conditions such that" is intended to cover both the situation where the sample is negative for the presence of the antigen and where the sample is positive for the presence of the antigen.

Claim 2 at lines 10-11 has been amended as in Claim 1. Support for the claim amendment is found particularly in paragraph 0022 of the present specification.

Claims 1 and 2 have been amended to recite the washing steps. Support is found in paragraphs 0021, 0022 and 0030 of the present specification.

In view of Applicant's amendments and arguments, reconsideration and withdrawal of the above ground of rejection is respectfully requested.

### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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